

REMARKS/ARGUMENTS

Claims 10-14, and 16-29 are currently pending in this application, all of which were rejected. Claim 10 has been amended to recite that the solution consists essentially of an effective amount of an amine. Support for the amendments to claim 10 can be found throughout the specification, specifically on page 5, last paragraph and on page 8, second paragraph of the specification. Claims 11, 13, 14, and 21-24 have been canceled. New claims 30-34 have been newly added. Support for new claims 30-34 can be found throughout the specification and in claims 10, 11, 13, and 14 as originally filed. Reconsideration and allowance of the claims is respectfully requested in view of the foregoing amendments and the following remarks.

1. Claims 18-24 are rejected under 35 U.S.C. § 102(e), as allegedly being anticipated.

Claims 18-24 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Birnie et al (Antimicrobial Evaluation of N-Alkyl Betaines and N-Alkyl-N,N-dimethylamine Oxides with Variations in Chain Length, Sept. 2000, Antimicrobial Agents and Chemotherapy, Vol. 44, No. 9, pp. 2214-2517. According to the Examiner, Birnie et al teach the antimicrobial activity of alkyl betaines and alkyldimethylamine oxides used either individually or in combination.

In response, applicants submit that claims 18-20 are directed to a method of inactivating a viral or microbial agent in a biological source material, comprising a step of contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldecylaminoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridexylamineoxide. Further, the term "consisting essentially of" refers to a solution which consists of the selected active ingredient and only minor amounts of non-essential ingredients, the active ingredient in claim 18-20 being the particular dimethylalkylamineoxide. Accordingly, applicants submit that the claimed invention in claims 18-20 is not anticipated by the cited reference. With respect to claims 21-24, applicants have cancelled claims 21-24 and therefore the rejection with respect to those claims is now moot. For these reasons, applicants respectfully request withdrawal of the rejections under 35 U.S.C. 102(e).

2. Claims 10-14, and 16-29 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious.

Claims 10-14, and 16-29 are rejected under 35 U.S.C. 103(a), as allegedly being obvious over Fonsny et al (US 5,911,915) in view of Rasmussen et al (US 2002/0022649 A1) as set forth on pages 5-8 of the Office Action. According to the Examiner, Fonsny et al disclose a stable, clear, multipurpose, hard surface cleaning composition especially effective in disinfecting the surface being cleaned. The Examiner asserts that the composition disclosed by Fonsny et al comprises among other ingredients 0.1% to 20% of a non-ionic surfactant and/or ethoxylated glycerol type compound, 0.1% to 20% of at least one disinfecting agent such as a cationic surfactant and 0.1% to 20% of an amphoteric surfactant. In addition, the Examiner asserts that Fonsny et al disclose a composition that preferably contains 0.25% to 8% of a disinfectant agent selected from C₈-C₁₆ alkylamines, and that amine oxides can be optionally used. According to the Examiner Fonsny et al does not disclose the exact ranges of each of the components claimed but asserts that the ranges in Fonsny et al overlap with the claimed ranges. Also, according to the Examiner Fonsny et al does not specifically disclose the inclusion of glycerol in the disinfectant composition but discloses the use of a non-ionic surfactant and Rasmussen et al discloses that glycerol is a non-ionic surfactant.

In response, applicants submit that claimed invention of claims 10, 12, 16-34 is directed to a method of inactivating a viral or microbial agent in a biological source material, comprising a step of contacting the biological source material with a solution, the solution may be consisting essentially of an effective amount of an amine or an amine in combination with a polyol or an amine oxide or an amine oxide in combination with a polyol, wherein the amine is selected from the group consisting of dimethyldecylamine, dimethyltridecylamine, dimethylundecylamine, dimethyldidecylamine, dimethyltetradecylamine, and dimethylhexadecylamine and the amine oxide is selected from the group consisting of: dimethyldecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide. Further, the term "consisting essentially of" refers to a solution which consists of the selected active ingredient amine or amine oxide, either with or without a polyol, and minor amounts of non-essential ingredients.

Furthermore, the present invention is directed to the use of biological materials as sources of medicinal and industrial intermediates and products. Due to the very nature of the biological materials or their methods of production, biological materials may contain

unwanted agents of viral origin that may be pathological or otherwise undesirable. The intended end-use of materials derived from biological sources may require a reduction in the biological activity of viral agents known to be present, or that are potentially present, in the source material or process additives. Reduction of viral activity in materials is commonly accomplished by a number of techniques including the use of heat, steam, pressure, chemical treatments and other methods. However, these techniques may irreversibly alter the properties of the biological source material or the desired substances to be obtained from same. As described in the specification on page 1, lines 8 to 25. In such cases, gentle, non-denaturing and specific methods are required to reduce the biological activity of viruses without damaging the desired molecules or substances of interest. Applicants submit that as described on page 5, lines 7-14 of the specification the claimed methods using alkyltrimethylamines or alkyltrimethylamine oxides alone as anti-viral or microbial agent do not denature or destruct the biomolecule of interest while inactivating a viral or microbial agent. In contrast, the cited references teach to use combinations of compositions wherein one of the components may be an alkyltrimethylamine or alkyltrimethylamine oxide. The compositions as taught by the cited references require an additional component in the solution necessary to the anti-infective properties thereof, whereas the claimed invention requires the solution to consist essentially of the alkyltrimethylamine or alkyltrimethylamine oxide, either with or without a polyol. Moreover, the cited references fail to teach or suggest to use a solution of an alkyltrimethylamine or alkyltrimethylamine oxide to inactivate a viral or microbial agent while not denaturing or destroying the biomolecule of interest.

With respect to claims 21-24, applicants have cancelled claims 21-24 and therefore the rejection with respect to those claims is now moot.

For these reasons, applicants submit that the claimed invention is neither taught or suggested by cited references. Accordingly, applicants respectfully request withdrawal of the rejections under 35 U.S.C. 103(a).

3. Claims 18-29 are rejected under 35 U.S.C. § 103(a), as allegedly being obvious.

Claims 18-29 are rejected under 35 U.S.C. 103(a), as allegedly being obvious over Michaels (US 5,389,676) as set forth on pages 8-10 of the Office Action. According to the Examiner, Michaels teaches compositions comprising surfactants including amine oxides for use in the formulation of disinfectants. In addition, the Examiner asserts that Michaels teaches the presence of betaine detergents in the anti-infective or disinfectant solution as well

as using a composition comprising 0.5% of C31G (a 1:1 betaine to amine oxide composition) and 5% glycerin (equivalent to glycerol). The Examiner states that Michaels does not specifically disclose a composition comprising one of the amine oxides in claims 18-29, however, the reference does disclose that dimethyldecylamineoxide is an example of an amine oxide useful in the anti-infective or disinfectant composition. According to the Examiner the skilled artisan would be motivated to use any of the amine oxides listed in Michaels with a reasonable expectation of success.

In response, applicants submit that as described above with respect to the rejection over Fonsny et al in view of Rasmussen et al, the method of the claimed invention of claims 18-20 and 25-29 requires the solution to consist essentially of alkyldimethylamine oxides, with or without a polyol. Further, as described above the claimed invention provides a method which does not denature or destroy a biomolecule of interest by using the solution consisting essentially of alkyldimethylamine oxides. In contrast, the compositions as taught by the cited reference require an additional component, in addition to the alkyldimethylamine oxide, in the solution necessary to the anti-infective properties thereof. However, the claimed invention requires the solution to consist essentially of the alkyldimethylamine oxide, either with or without a polyol. Moreover, the cited reference fails to teach or suggest to use a solution of an alkyldimethylamine oxide to inactivate a viral or microbial agent while not denaturing or destroying the biomolecule of interest.

With respect to claims 21-24, applicants have cancelled claims 21-24 and therefore the rejection with respect to those claims is now moot.

For these reasons, applicants submit that the claimed invention is neither taught or suggested by cited references. Accordingly, applicants respectfully request withdrawal of the rejections under 35 U.S.C. 103(a).

It is believed that claims 10, 12, 16-20, and 25-34 are now in condition for allowance, early notice of which would be appreciated. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same.

Respectfully submitted,

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